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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/671,995	09/29/2000	Ravi V. J. Chari	104322.198 US1	2588

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EXAMINER	
CANELLA, KAREN A	
ART UNIT	**PAPER NUMBER**
1643	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/671,995	CHARI, RAVI V. J.	
	Examiner	Art Unit	
	Karen A. Canella	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *93-105 and 114-149* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *93-105 and 114-149* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 93-105 and 114-149 are pending and under consideration.

After review and reconsideration, the finality to the Office action of August 9, 2006 is withdrawn.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 93-105 and 114-149 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for synergistic combinations of topoisomerase inhibitors or a microtubule inhibitors with an immunoconjugate targeting a cancer cell antigen, wherein said immunoconjugate comprises a maytansinoid, does not reasonably provide enablement for a synergistic combination of any chemotherapeutic agent with an immunoconjugate targeting a cancer cell antigen, wherein said immunoconjugate comprises a maytansinoid. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. In re wands, 858 F.2d 731, 737.8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The specification teaches and the instant claims require a synergistic combination of a chemotherapeutic agent and an immunoconjugate which binds to a antigen expressed by cancer cells, wherein said immunoconjugate comprises a maytansinoid. The specification specifically demonstrates a synergistic interaction between the N90-DM1 immunoconjugate in combination with paclitaxel, docetaxel, topotecan and the combination of cisplatin and etoposide. Thus, the

specification demonstrates that the delivery of the maytansinoid to a cancer cell via an immunoconjugate can synergize with chemotherapeutic agents which are microtubule inhibitors (paclitaxel and docetaxel, Fitzpatrick and Wheeler, International Immunopharmacology, 2003, Vol. 3, pp. 1699-1714, see lines 1-3 of the abstract) or topoisomerase inhibitors (topotecan and etoposide, Fedier et al, Annals of Oncology, 2003, Vol. 14, pp. 938-945, see page 938, lines 2-3 in the "Results" portion of the abstract). It is noted that no demonstration of synergisms was provided for cisplatin in the absence of a topoisomerase inhibitor. Claims 93-96, 98-105 encompass combinations of immunoconjugates bearing maytansinoid species with chemotherapeutic agents which are not microtubule inhibitors or topoisomerase inhibitors. Claims 97, 144, 145, 148 and 149 encompass a combination of an immunoconjugate bearing a maytansinoid species with cisplatin as a sole chemotherapeutic agent. The art recognizes that the combination of anti-cancer agents can result in a synergistic, additive or antagonistic interaction. The art also recognizes that synergism is an unexpected result and cannot be predicted, but rather must be determined empirically (Gerson et al, WO03/070234, page 2, lines 7-15). Specifically Pegram et al (Oncogene, 1998, Vol. 18, pp. 2241-2251) teaches that the combination of a chemotherapeutic agent used to treat breast cancer with the Her-2 antibody can produce synergism with certain chemotherapeutic agents such as cisplatin in combination with etoposide, additive effects which in combination with doxorubicin, paclitaxel, methotrexate or vinblastine, or antagonistic effects in combination with 5-FU (abstract). This serves to demonstrate that one of skill in the art would not have a reasonable expectation of success for making and using the broadly claimed combinations of chemotherapeutic agents and maytansinoid immunoconjugates and therefore would be forced into undue experimentation.

All other rejections and objections as se forth or maintained in the previous Office action are withdrawn in light of applicants arguments.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Karen A. Canella, Ph.D.
01/21/2007

KAREN A. CANELLA PH.D
PRIMARY EXAMINER